



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our reference: 2953910

November 2, 2000

Lawrence M. Ravitz, Owner
Banner Mountain Sprouts
3351 Fruitridge Rd.
Sacramento, CA 95820

WARNING LETTER

Dear Mr. Ravitz:

An inspection of your sprout growing operation was conducted on July 17 and 19, 2000, by Investigator Janice R. Lathan of this office. At the conclusion of the inspection you were issued a Form FDA-483 (copy attached) which outlined insanitary conditions present in your firm at the time of that inspection.

These conditions cause the sprouts manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act), because the sprouts were prepared, packed, and held under conditions whereby they may have become contaminated with filth or rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented at your facility.

This letter is not intended to be an all-inclusive review of deficiencies. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include a seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Please address your response to Suzanne Schenck, Compliance Officer.

Sincerely,

A handwritten signature in cursive script that reads "Charles D. Moss".

Charles D. Moss
Acting District Director
San Francisco District

Enclosure: FDA-483